

Fitzpatrick

FITZPATRICK, CELLA, HARPER & SCINTO

HENRY J. RENK
hrenk@fchs.com
212-218-2250
www.fitzpatrickcella.com

NEW YORK
1290 Avenue of the Americas
New York, NY 10104-3800
T 212-218-2100
F 212-218-2200

October 31, 2011

VIA ECF

Honorable Joel A. Pisano, U.S.D.J
U.S. District Court for the District of New Jersey
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street
Trenton, New Jersey 08608

Re: AstraZeneca AB et al. v. Hanmi USA, Inc. et al.
Case No.: 11-cv-00760-JAP-TJB

Dear Judge Pisano:

We, along with McCarter & English, represent the AstraZeneca plaintiffs in this matter. Last Monday, October 24, the parties discussed with Your Honor the scheduling of defendant Hanmi's pending five summary judgment motions (D.I. 97-117 called Motions 1-5 in this letter). At that time, the parties agreed to further discuss that scheduling, and the Court has scheduled a follow-up telephone conference at 10 am tomorrow to address this issue. In advance of tomorrow's call, we write to advise the Court of the status of the parties' discussions and to request the Court's assistance in resolving the remaining scheduling disputes.

Background

This case involves the validity and infringement of two AstraZeneca patents: U.S. Patent No. 5,714,504 ("the '504 patent") and U.S. Patent No. 5,877,192 ("the '192 patent"). In claim construction proceedings in an earlier case, *AstraZeneca A.B., et al v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 05-cv-5553, this Court on May 18, 2010 construed certain language in the claims of both the '504 and '192 patents.

Claim construction proceedings in the present case are now underway. Under the existing schedule, initial *Markman* submissions were due to be filed today, October 31, 2011. As explained below, in order to accommodate and address the new claim construction issues interjected by Hanmi in its summary judgment motions, AstraZeneca has proposed to Hanmi that certain dates in the present claim construction proceedings be adjusted. Hanmi has not agreed to these proposed adjustments, but the parties have agreed, subject to the Court's approval, to extend today's due date by one week, to November 7, 2011. This will hopefully allow sufficient time for the Court to resolve this dispute.

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Two constructions from the *Dr. Reddy's* case are relevant to the present scheduling disputes. First, claim 1 of the '504 patent recites a pharmaceutical formulation comprising a pure "solid state" alkaline salt of esomeprazole. This Court in *Dr. Reddy's* determined that no construction of "solid state" is necessary because "its ordinary and customary meaning would be clear to one skilled in the art" and "[t]herefore, the plain meaning of the term as understood by someone of ordinary skill shall apply." *Dr. Reddy's*, 2010 WL1981790 (D.N.J.) at *9. During the claim construction process here, Hanmi indicated that it was adopting this ruling. As discussed below, despite its adoption of this Court's claim construction from *Dr. Reddy's*, Hanmi, in its Motion 3, asserts that "solid state" has *no* art-recognized meaning.

Second, a number of the '192 patent claims are directed to a method of treatment comprising administering esomeprazole "so as to effect" a certain biological result (e.g., claim 1 refers to "decreased interindividual variation in plasma levels (AUC)"). In *Dr. Reddy's*, this Court declined to construe "so as to effect" because "its ordinary and customary meaning would be clear to one skilled in the art," but the Court also determined that the various biological results should be construed to mean the particular result obtained with esomeprazole *compared to the result obtained with omeprazole*. *Id.* at *10–19. Thus, in the case of '192 patent claim 1, the claim was interpreted to mean "so as to effect a reduced difference or deviation in blood levels of [esomeprazole], as measured by the area under the concentration-time curve, compared to the blood levels of omeprazole, as measured by the area under the concentration-time curve." *Id.* at *13 (emphasis added). Significantly, in its earlier construction, the Court did *not* conclude that any additional clinical evaluation was necessary to compare esomeprazole to omeprazole. But, in its Motion 1, despite its adoption of the Court's prior construction (D.I. 98 at 6–8), Hanmi now alleges that some additional clinical evaluation is necessary.

These new claim construction positions presented by Hanmi in its summary judgment motions necessitate both (1) adjusting the existing claim construction schedule in the present case to allow consideration of the impact of Hanmi's new claim construction positions on the Court's claim constructions from *Dr. Reddy's* and (2) postponing any consideration of Hanmi Motions 1 and 3 until *after* those new claim construction issues are resolved.

Hanmi Motion 1

In its Motion 1 (D.I. 97–98), Hanmi alleges non-infringement of the '192 patent claims 1–11, 13–18 and 20–23 principally based on its theory that infringement requires some additional "active determination" or some additional "clinical evaluation" of a particular clinical benefit of esomeprazole as compared to omeprazole. D.I. 98 at 3–4. Hanmi concedes that some reinterpretation or reconsideration of the Court's previous claim construction is necessary to determine whether and to what extent the '192 patent claims must be construed to require the additional "comparative evaluation" Hanmi now says is required. *Id.* at 8–11.

Although AstraZeneca disagrees that the '192 patent claims require the additional "comparative evaluation" relied on by Hanmi, at a minimum this is a claim construction issue best resolved during the present claim construction proceedings. It makes no sense, as proposed by Hanmi, to

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address this claim construction issue in the context of Hanmi's summary judgment Motion 1, when other claim construction issues are already being addressed in the ongoing claim construction proceedings in the present case. The only thing that makes sense is to postpone consideration of Hanmi Motion 1 until after completion of claim construction proceedings in the present case.

To that end, AstraZeneca proposes that the Court adopt the revised claim construction schedule set forth in attached Exhibit A. This proposal includes a modest postponement of about two months in the existing claim construction schedule, and it has the advantage of resolving all claim construction issues together. In contrast, Hanmi would effectively bifurcate claim construction, some issues to be dealt with in the course of the existing claim construction proceedings and some other claim construction issues—the ones raised by Hanmi its summary judgment Motion 1—to be dealt with in the course of dealing with Hanmi Motion 1.

Hanmi Motion 2

The parties have agreed on a briefing schedule for Hanmi Motion 2 (D.I. 99–100); a proposed order will be submitted for the Court's approval.

Hanmi Motion 3

Hanmi alleges in Motion 3 (D.I. 101) that certain claims of the '504 patent are invalid under 35 U.S.C. Section 112, first and second paragraphs, on three separate grounds. In particular, and contrary to Hanmi's adoption of this Court's claim construction in *Dr. Reddy's*, in which this Court determined that "solid state" would be understood by a person of ordinary skill in the art, Hanmi now alleges for the first time that "solid state" has *no* art-recognized meaning. As a result, according to Hanmi Motion 3, claims of the '192 patent containing that term are invalid because 1) they allegedly are indefinite; 2) they allegedly are not enabled by the patent specification; and 3) allegedly there is no written description of the claimed invention in the patent specification. D.I. 101-2.

Having adopted the Court's previous claim construction ruling, Hanmi should be precluded from now challenging it, which, effectively, is what Hanmi proposes to do in its Motion 3.

At a minimum, should Hanmi be permitted to assert the defenses raised in its Motion 3, resolution of that motion requires the Court to determine whether "solid state" has a meaning to a person of ordinary skill in the art, and what that meaning is. Those determinations should be made in the ongoing claim construction proceedings in this case, as AstraZeneca proposes, and not during consideration of Hanmi's summary judgment Motion 3, as Hanmi proposes. It makes little sense to bifurcate claim construction issues, which would happen under the scenario proposed by Hanmi. What makes the most sense is to adopt the modest postponement of the ongoing claim construction proceedings as set forth in attached Exhibit A, which would permit consideration of the meaning of "solid state," and to postpone any consideration of Hanmi's Motion 3 until after completion of the claim construction proceedings.

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Hanmi Motion 4

In Motion 4 (D.I. 102–103), Hanmi alleges that the asserted claims of the '504 patent are invalid for lack of a written description and for non-enablement under Section 112. Specifically, Hanmi alleges that there is no written description in the patent of hydrated forms of alkaline salts of esomeprazole, and that the patent does not enable one of ordinary skill in the art to make such hydrated forms. D.I. 103. These specific arguments are new; Hanmi never made them in its invalidity contentions served on May 25, 2011. Accordingly, until Hanmi successfully seeks leave to amend its invalidity contentions to assert these specific new defenses, pursuant to Local Patent Rule 3.7, its Motion 4, is premature.

In support of its argument that these "hydrate" defenses are not new, Hanmi points to pages 67–70 and 71–73 of its invalidity contentions (copy of those pages attached as Exhibit B). As is apparent from any reasonable reading of these pages, Hanmi's written description and non-enablement defenses described there are based only on its assertion that the '504 patent does not describe or enable "alkaline" salts of esomeprazole other than the salts specifically exemplified in the patent. Nowhere did Hanmi expressly allege the new argument of invalidity based on an alleged failure to describe or enable hydrates of esomeprazole. Thus, Hanmi Motion 4 is premature.

Hanmi Motion 5

Hanmi Motion 5 (D.I. 104) seeks a summary judgment of non-infringement of claims 8 and 9 of the '504 patent on the sole basis that such claims are not asserted against Hanmi in this case. AstraZeneca will not oppose that part of Hanmi's Motion 5. However, Hanmi seeks the same relief with respect to claims 3, 5 and 10 of the '504 patent. As to those claims, Hanmi's Motion 5 is premature; AstraZeneca has moved to add claims 3, 5 and 10 to the claims being asserted in this case. *See* D.I. 81, 82, 86, 90. Plainly, resolution of that part of Hanmi's summary judgment Motion 5 must await the Court's resolution of AstraZeneca's motion to add those claims.

* * *

For the reasons given above, AstraZeneca respectfully requests (1) that Hanmi's summary judgment Motion 1 be precluded, or at least that its briefing and resolution be postponed until after completion of the present claim construction proceedings; (2) that the claim construction proceeding schedule be modified as set forth in Exhibit A; (3) that briefing and resolution of Hanmi's summary judgment Motion 3 similarly be postponed until completion of the present claim construction proceedings; (4) that briefing and resolution of Hanmi's summary judgment Motion 4 be postponed until after Hanmi successfully obtains leave to amend its invalidity contentions to assert the new defense asserted in that motion; and (5) Hanmi's Motion 5 be dismissed at least until Hanmi can formally amend its pleadings to add the defenses which form the bases of this motion.

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Counsel for AstraZeneca are available for a conference on these issues at the Court's convenience.

Respectfully submitted,

Henry J. Renk /MEF

Henry J. Renk

cc: Hon. Tonianne J. Bongiovanni (via ECF and email)
Counsel of record (via email)

Enclosure